DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

INGRID MEHLHORN,
SENIOR MANAGER, REGULATORY AFFAIRS
SIEMENS HEALTHCARE DIAGNOSTICS INC.
725 POTTER STREET,
BERKELEY, CA 94710 US

December 19, 2016

Re: EUA160014/A001
Trade/Device Name: VERSANT Zika RNA 1.0 Assay (kPCR) Kit
Dated: December 9, 2016
Received: December 14, 2016

Dear Dr. Mehlhorn:

This is to notify you that your request to modify the Fact Sheets authorized with the VERSANT Zika RNA 1.0 Assay (kPCR) Kit to combine the Fact Sheet for Patients and the Fact Sheet for Pregnant Women into one Fact Sheet for Patients and to include updated language to align with the latest CDC Zika Laboratory Guidance, implemented in November 2016, has been granted. By submitting this amendment for review by FDA, you have complied with the Conditions of Authorization stated in the letter authorizing the emergency use of the VERSANT Zika RNA 1.0 Assay (kPCR) Kit issued July 29, 2016.

Sincerely yours,

Uwe Scherf, M.Sc., PhD.
Director
Division of Microbiology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure